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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,434	09/09/2008	Igor E. Bondarev	ALTS.0006US2	5607

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EXAMINER	
PITRAK, JENNIFER S	

ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
12/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

iplaw@stites.com

Office Action Summary	Application No.	Applicant(s)	
	10/586,434	BONDAREV ET AL.	
	Examiner	Art Unit	
	JENNIFER PITRAK	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18-20,22-24 and 62-64* is/are pending in the application.

4a) Of the above claim(s) *3-5 and 18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6-16,22-24 and 62-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on 08/25/2010 is acknowledged. The traversal is on the ground(s) that all inventions (groups) are linked so as to form a single general inventive concept. This is not found persuasive because the special technical feature of the inventions, administering a telomerase inhibitor to treat cancer, does not contribute over the prior art. Woo, et al. (US Patent 5,631,236) teach administering a telomerase inhibitor to treat cancer as indicated in the rejections presented herein. Applicant also argues that there is no undue burden to consider all pending claims. This is not persuasive. Each invention requires a distinct search and subsequent review of the results of such search. The burden on the examiner to search each invention, therefore, is undue.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election with traverse of the species, **ganciclovir**, **osteosarcoma**, and **oral administration** in the reply filed on 08/25/2010 is acknowledged. The traversal is on the ground(s) that there is no reason for insisting on the election of species and no undue burden on the Examiner. This is not found persuasive because, contrary to Applicant's assertions, a search for the subject matter of one species would not necessarily encompass a search for the other species in the group. This is evidenced by the fact that a search of the elected species did not reveal subject matter pertaining to all non-elected species.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-16, 18-20, 22-24, and 62-64 are pending. Claims 3, 4, 5, 18, 19, and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 08/25/2010. It is noted that claims 3-5 depend from claim 1. However, the claims are directed to an antisense sequence, which is first recited in claim 2. Therefore, claims 3-5 are interpreted as depending from claim 2 and being directed to methods comprising the administration of an antisense sequence, which is a non-elected invention.

Claims 1, 2, 6-16, 22-24, and 62-64 are under examination.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing. The Oath identifies United States Application No. 10/758329 under foreign priority. This U.S. application is not a foreign application. Furthermore, the Oath does not indicate the priority claim to U.S. Provisional Application 60/440,988. The first paragraph of the specification indicates that such priority is claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites the limitation "the cancer". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 6-16, 22-24, and 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woo, et al. (U.S. Patent 5,631,236) as evidenced by Bryan, et al. (2000, Nat. Med., v.3:1271-4) (of record, item CV on 09/09/2008 IDS) ("Woo").

The claims are directed to methods of treating cancer by administering a nucleoside analog. Claim 10 specifies that the cancer cells show alternative lengthening of telomeres (ALT) and LINE-1 reverse transcriptase (L1RT) activity. According to the instant specification, cells exhibiting ALT depend on L1RT for elongating or maintaining telomeres (see paragraph

spanning pages 9 and 10). Thus, ALT cells are understood to have L1RT activity.

Woo teaches methods of treating solid tumors, including bone tumors (osteosarcoma), by administering ganciclovir (abstract; column 3, lines 21-25; claims 1-6). At column 4, lines 14-22, Woo teaches that ganciclovir can be administered by a person having ordinary skill in the art and that such person would readily be able to determine the most appropriate dose and route for the administration of ganciclovir. This is further supported by the instant specification at pages 18, 26, and 30. Woo does not teach that the tumor cells exhibit ALT or L1RT activity. However, Bryan, et al. teach that some cancer cells have ALT activity (ALT^+ cells), including some osteosarcoma cells and that ALT^+ cells are telomerase-negative (p. 1271, Table 1; page 1272, Figure 1 and Table 2).

It would have been obvious to one of skill in the art at the time the instant invention was made to treat solid tumor cancers with ganciclovir because Woo teaches such a method. It would have been obvious to treat cancer, including those having ALT activity and those lacking ALT activity (ALT^-), because one of skill in the art would recognize the methods of Woo to be applicable to both ALT^+ and ALT^- cancers. Such ALT^+ cancers are understood to have L1RT activity, as indicated above. It would have been obvious to administer ganciclovir orally, parenterally, subcutaneously, intramuscularly, or intravascularly and at a dosage of between 100 to 500 mg/kg body weight per day because Woo teaches that a person of skill in the art would readily be able to determine the most appropriate dose and route for the administration of ganciclovir. Furthermore, specifically relevant to the instant claim 15, Woo teaches methods of treating solid tumors by administering a nucleoside analog, acyclovir, at a preferred dosage of 1-100 mg/kg of body weight per day (column 4, lines 19-20; claim 4). It would have been obvious

to administer two nucleoside analogs because Woo teaches several nucleoside analogs that can be used in the methods and one of skill in the art would reasonably expect that combining the use of two nucleoside analogs in the methods of Woo would result in equivalent if not better results than that achieved with a single nucleoside analog. Absent evidence to the contrary, such administration of a nucleoside analog such as ganciclovir as taught by Woo would result in blocking the lengthening of telomeres.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 6-16, 22-24, 62, 63, and 64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 59-85 of copending Application No. 12/070923. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '923 application are directed to species of the instant claims and therefore the '923 claims anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 6-16, 22-24, 62, 63, and 64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 16-33 of copending Application No. 11/920668. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '668 application are directed to the same methods of treating cancer in cells showing ALT activity comprising administering ganciclovir and other nucleoside analogs.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 6, 10, 14, 16, and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 46 of copending Application No. 12/225199. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the '199 application is directed to a method of treating cancer by administering a nucleoside analog L1RT inhibitor or inhibitors, which is also instantly claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Heather Calamita can be reached on 571-272-2876. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Pitrak/
Examiner, Art Unit 1635